

NIH POLICY MANUAL

54513 - MANAGEMENT AND PROCEDURES OF NATIONAL ADVISORY COUNCILS AND BOARDS IN THEIR REVIEW OF EXTRAMURAL ACTIVITIES

Issuing Office: OER 496-1964

Release Date: 05/15/95

1. Explanation of Material Transmitted: This chapter contains revised and updated policy for the management and procedures of National Advisory Councils or Boards in their review of extramural activities.
2. Material Superseded: This issuance incorporates I&I Memoranda OERT 86-11, OER 87-11, and OER 87-15 which are therefore cancelled.
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A. Purpose:

This chapter states the requirements and policy for the management and review procedures of National Advisory Councils or Boards, hereinafter referred to as Councils, in their review of NIH extramural programs as well as grant and cooperative agreement applications.

B. Applicability:

This policy applies to all NIH Institutes and Centers (ICs) having Councils that advise, consult, and recommend on matters related to the activities of the operating components and the policies concerning such activities.

C. Primary References:

1. Public Health Service Act as amended, 42 USC 241, 42 USC 284a.
2. [NIH Manual Chapter 1805](#), Use of Advisors in Program and Project Review and Management.
3. [NIH Manual Chapter 1810-1](#), Procedures for Avoiding Conflict of Interest for Special Government Employee Advisory Committee Members (pending release).
4. [NIH Manual Chapter 3005](#), Review and Evaluation of Intramural Programs.
5. [NIH Manual Chapter 4104](#), NIH Research Grants to Foreign Institutions and International Organizations
6. [NIH Manual Chapter 4107](#), Review of Applications and Award of Grants Involving Human Subjects.
7. [NIH Manual Chapter 4206](#), Responsibility for Care and Use of Animals.
8. [NIH Manual Chapter 4518](#), Peer Review Rebuttals and Appeals.
9. NIH Manual Chapter 7110, Inclusion of Minorities and Women as Subjects in Research (Formerly I&I OER 90-5) (in preparation).

D. Legislative Authority:

The Public Health Service Act, as amended, requires that the Secretary (or, for the National Cancer Advisory Board, the President) shall appoint an advisory council for each national research institute which shall ... advise, assist, consult with and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities ... (PHS Act, Section 406(a)(1)). [Note: unless otherwise specified, hereafter, reference to "Section" pertains to the PHS Act.]

The Council of each national research institute ... may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under Section 405(b)(2), and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge ... (Section 406(a)(3)(A)(ii)). Funding of a grant or cooperative agreement may occur only after if it has been favorably recommended by an initial review group (see Section 405(b)(2)(B)(i)). In addition, with the exception of domestic applications for grants and cooperative agreements (for research, training, or demonstrations) which do not exceed an amount specified in law, awards may not be made without concurrence by the advisory council for the national research institute involved (see Section 405(b)(2)(B)(ii)). This exception applies to individual fellowship awards under the ceiling, but not to institutional training awards (see Section 487(b)(2)). (At this writing, the exception does not apply to Centers or the NLM which do not fall under the same authorization--see below.)

Councils of the national research institutes are also involved in the review of intramural research programs (Section 492(b)) and make recommendations on the acceptance of gifts (Section 406(a)(2)); however, such activities are beyond the scope of this manual chapter.

The Fogarty International Center (FIC), the National Center for Human Genome Research (NCHGR), the National Library of Medicine (NLM), and the National Center for Research Resources (NCRR) are not covered by the above citations, although their Councils or Boards serve essentially the same functions. The FIC and the NCHGR are covered under the general PHS authority: "The Secretary may delegate to such council ... such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council ... is concerned, as the Secretary determines to be appropriate" (Section 222(c)). The NLM and NCRR are authorized separately under Sections 466 and 480 respectively.

E. Policy:

1. Extramural Program Review - Consistent with the charter of each council or board (hereafter, Council), the Director of each IC may establish a system for the Council to: 1) periodically review extramural programs, and 2) make recommendations about research activities. The periodicity and depth of these programmatic reviews may be established by the IC Director with advice from the Council. The purpose of this review by Council is to:

- provide advice on the use of grant, cooperative agreement, and contract funds in the IC's portfolios and conduct of research and related activities;
- obtain information and provide advice on program management and administration;
- ensure IC responsiveness to public needs;

- encourage initiatives for the support of high quality science; and
- assist the IC in establishing objectives and priorities, in identifying resource allocation factors, and in enhancing program management and effectiveness.

2. Application Review - National advisory councils provide the second level peer review of applications for grants and cooperative agreements.

3. Intramural Program Review - As noted earlier, the intramural review function of Council is beyond the scope of this manual chapter (see [NIH Manual 3005](#)).

F. Implementation:

1. Operating Procedures for Application Review - Operating procedures to be used by Councils are to be developed by the IC with the advice of Councils and in conformity with peer review regulations and NIH policy. Such procedures are to be reviewed annually at a meeting of the Council. When these procedures are initially established or substantially changed, they are submitted to the Deputy Director for Extramural Research (DDER), OER or designee who will review for compliance with NIH policy and peer review regulations. Requirements and key features are summarized with suggested procedures in Appendix 1.

2. Administrative Procedures:

- Conflict of Interest/Waivers* - NIH Manual Chapters [1805](#) and [1810-1](#) provide guidance for handling conflict of interest matters for Special Government Employee Advisory Committee Members.
- Confidentiality* - All materials relating to the review of grant and cooperative agreement applications, including initial review summary statements and staff recommendations must be treated as confidential by Council members. Members must not discuss review proceedings with anyone outside the Council or the NIH and must refer to the appropriate staff any inquiries from applicants or others about pending applications.
- Quorum/Voting Members* - Unless otherwise established by statute or by the Council charter, a quorum is a majority of the authorized membership of the Council. Unless otherwise established by statute or by Council charter, ex officio members, but not liaisons, shall be included in establishing a quorum.

For Councils established under Section 406, ex officio members are non-voting. Thus, only those ex officio members of the Councils of the National Library of Medicine (NLM), National Center for Research Resources (NCRR), Fogarty International Center (FIC), the National Center for Human Genome Research (NCHGR), and the National Institute of Nursing Research (NINR) are voting members.

3. Review of Applications - At a minimum, with the exception of those applications not requiring Council review as noted in Section D. above, each IC must present for Council review all applications that may be considered for funding and any applications involving rebuttals that require Council action. The IC Director, with consultation by Council, may determine whether other applications are to be presented routinely to Council. Council consideration may take either of two forms: Action on Individual Applications or En Bloc Action.

a. *Consideration of Applications Individually*

(1) Each IC, with its Council, shall determine circumstances that warrant identifying particular kinds of applications for individual discussion. Criteria could include, for example, size, support mechanism, or subject matter.

(2) Applications involving rebuttal letters that require Council action are individually considered. Council responsibilities for reviewing rebuttals are detailed in [NIH Manual 4518](#).

(3) Applications to be considered for funding by the IC must be brought to the attention of Council if they involve any of the following:

- applications with procedures or conditions that may violate policies related to animal welfare (codes 44 and 49) (see [NIH Manual 4206](#));
- all applications with procedures or conditions that may violate policies related to the welfare of human subjects (codes 44 and 49)(see [NIH Manual 4107](#));
- all studies with concerns about the representation of gender and/or minorities (any codes ending with "U")(see NIH Manual 7110 pending release); or
- applications from foreign institutions (see [NIH Manual 4104](#)).

Councils will also specifically review:

- nominations that have been identified for MERIT awards; and
- applications for extension of MERIT Awards.

(4) In addition to applications identified above, the IC Director or any Council member may ask that any individual application or group of applications be discussed.

- b. *En Bloc Action* - Applications not considered individually may be acted upon as a group. When a Council concurs with the recommendations made in initial review on a group of applications, the Council may, without any conflict of interest implications, vote en bloc concurrence with the initial review recommendations.

4. Disagreement Between Council and Initial Review Recommendations - Procedures for resolving and documenting instances where applications recommended by initial review are not recommended by Council, or vice versa, are presented in Appendix 1. Disagreements by Council may be based on scientific and technical merit, or other considerations. When a Council decision on recommendation is based on scientific and technical merit, such an application may be deferred for re-review. If after re-review the Council still disagrees with the recommendation of initial reviewers based on scientific and technical merit, the Council should note this in the record. Applications may not be considered for funding unless recommended by both the initial review and the Council. A Council decision not to recommend an application with a favorable initial review for reasons other than scientific and technical merit may be based on a variety of considerations, including several of those listed under F.3.a. (above).

Such applications need not be deferred for re-review by an initial review group, but the issues may be resolved by NIH staff as befits the situation. If issues are resolved to Council's satisfaction, such applications could be considered for funding.

5. Notation System for Council Actions - A Council may not change the numerical ratings (e.g., priority score, percentile) resulting from the initial review. However, the Council may recommend that the IC change the order of consideration of certain applications for funding. The following codes shall be used to indicate Council action in relation to the numerical rating:

- CON (Concurrence) - Concurrence with initial review favorable recommendation and numerical score;
- HPP (High Program Priority) - Raised in order of consideration for funding;
- LPP (Low Program Priority) - Lowered in order of consideration for funding;
- OTH (Other) - Council favorable recommendation of an application that did not receive a favorable initial review, or an unusual action that cannot be identified as CON, HPP, or LPP, such as changes in recommended budget and/or duration of support. Use of this code is optional at the IC's discretion.

In addition, a Council may specifically recommend that an application receiving a favorable recommendation in initial review, not be considered for support. In such a case, the following designation would be used:

NRC (Not Recommended by Council) - Not recommended by Council and, thus, may not be considered for funding.

G. Records Retention and Disposal:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in [NIH Manual Chapter 1743](#), Appendix 1 -- "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1100-H-2. Refer to the NIH Manual Chapter for specific disposition instructions.

Appendix

Announcement and Closure of Council Meetings

In accordance with the Federal Advisory Committee Act, all Council meetings must be announced in the Federal Register at least 15 days before the date of the meeting. Council meetings shall be open, but may be closed in accordance with provisions of the Government in the Sunshine Act (P.L. 94-409) during the review of grant or cooperative agreement applications. Closed meetings are permitted when the discussion of applications is likely to "...disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential..." and personal information concerning individuals associated with the application, "...where disclosure would constitute a clearly unwarranted invasion of privacy." Closing of meetings or portions of meetings must be approved by formal determination by the NIH Office of the General Counsel.

Selecting Criteria for Individual Consideration of Applications

Applications most often brought up for specific discussion include those in which:

- a policy issue has been identified;
- there is a split vote (two or more IRG members dissenting) or other minority reports from the IRG;
- some aspect of the IRG recommendation is questioned or cannot be resolved by IC Staff;
- the recommended budget is unusually large;
- the research objectives proposed are of particular interest or concern to the IC.

Administrative Decisions and Actions that Do Not Require Council Recommendations

The following staff actions do not require Council recommendations but may be presented to the Council for information purposes:

- change of principal investigator or program director on a project that will continue to receive support at the same grantee institution;
- change of institution by a principal investigator who will receive previously recommended support for the project continuing at the new institution;
- administrative actions mutually agreed upon between the IC and Council in the formal operating procedures that have been adopted;
- applications deferred for re-review prior to the Council meeting;
- for the national research institutes (this excludes NLM, FIC, NCRR, and NCHGR), those applications for which an award to a domestic institution is to be made that has been scored by an IRG and does not exceed \$50,000 in direct costs for any 12-month budget period.

Annual Council Activity Documentation

The Federal Advisory Committee Act requires that committees whose meetings are determined to be closed to the public shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with their having "closed" meetings. Since council meetings are only partially closed to the public, the minutes of the open portions should not include any information that might compromise the closed sessions. Guidelines for the minutes and the annual reports are provided by the NIH Committee Management Office.

Council Procedures Review

Each awarding component (IC) shall develop, with the advice of Council, operating procedures for the review of applications. These procedures would include, for example, IC-specific rules concerning which applications are reviewed or given special attention, or how council subcommittees, if any, are constituted. These procedures must be reviewed once each year with Council members with the understanding that they also must be approved by the Deputy Director for Extramural Research (DDER), OER. The DDER will review procedures for compliance with peer review regulations and NIH policy when they are first established. Any substantial revision of these procedures must be provided to the DDER for review in a timely way.

Documentation and Procedures Relating to Council Non-concurrence

A written statement documenting the rationale for Council non-concurrence with any initial review recommendation shall be provided by IC staff to the appropriate SRA within ten (10) working days after the Council meeting.

For all Council deferrals, the Referral Section, Referral and Review Branch, DRG, will serve as the focal point for subsequent actions. In addition to the written rationale (see above), IC staff will complete appropriate forms (as specified below) and forward them to the Referral Section within 10 days following the Council meeting. When the deferral is for re-review of an application originally reviewed by DRG, the tracking chart (See Appendix 3) is required. IC staff may contact the Principal Investigator regarding a Council recommendation for re-review only after the appropriate documentation has been provided to DRG and agreement has been reached between the IC and DRG about the re-review.

Disagreements concerning re-review of an application are resolved by the Associate Director for Extramural Affairs, NIH. When deferral for re-review involves initial review conducted in an IC, or when applications are deferred for subsequent Council consideration without re-review, the Council Deferral Tracking Chart and a Change Request Form must be submitted along with the written rationale. The Change Request Form should show the change in Council date and/or IRG assignment. The Grant/Application Change Notice (Form NIH 901-1) is used to change budgets or project periods. The DRG Referral Section will take appropriate action and notify appropriate staff.

When the Council action differs from the initial review group recommendation, the letter notifying the principal investigator/applicant institution of the Council's recommended action will also explain its variant action.

The official files must contain documented explanations of any actions identified as OTH. For those applications reviewed by an initial review group, a copy of the documentation shall be forwarded to the SRA's office.

1. PHS Grants Administration Manual, Part 118, Ranking, Approval and Funding of Grant Applications, and Notification to Unsuccessful Applicants.
2. PHS Grants Administration Manual, Part 134, Objective Review of Grant Applications.
3. [NIH Manual Chapter 4510](#), Referral and Initial Review of NIH Grant and Cooperative Agreement Applications.
4. [NIH Manual Chapter 4511](#), Project Site Visits Involving Review of Grant and Cooperative Agreement Applications.
5. [NIH Manual Chapter 4512](#), Summary Statements.

6. [NIH Manual Chapter 4514](#), Role of Staff at Peer Review Advisory Committee Meetings and Exchange of Information Among Review, Program and Grants Management Staff.
7. [NIH Manual Chapter 4515](#), Guidelines for Dually Assigned Grant Applications.
8. [NIH Manual Chapter 4516](#), Review of Institutional National Research Service Award Applications.
9. [NIH Manual Chapter 4517](#), Review of Program Project Grant Applications.
10. [NIH Manual Chapter 4815](#), Implementation of Cooperative Agreements - Initiation, Review, Award, and Administration.